

6 510(k) Summary

K080997 pg 1 of 2

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, #100
Austin, TX 78754-3832

510(k) CONTACT: Debbie Stearns
Phone: (512) 836-5001 x1548

JUN 17 2008

TRADE NAME: Ascension® PyroCarbon Lunate

COMMON NAME: Prosthesis, Wrist Carpal Lunate

CLASSIFICATION: 21 CFR 888.3750

PRODUCT CODE: KWN

PANEL: Orthopedic

PREDICATE DEVICES:

K864491 – Swanson Titanium Carpal Lunate Implant

K061451 – Ascension PyroCarbon CMC

DEVICE DESCRIPTION:

The Ascension® PyroCarbon Lunate is an anatomically designed lunate replacement with essentially the same shape as the native lunate bone. The Lunate implant acts as an articulating spacer to maintain the relationship of adjacent carpal bones after excision and to maintain mobility of the wrist. The articular concavity that captures the capitate is more exaggerated to enhance stability. The Lunate implant has two suture holes that allow fixation of the implant to the adjacent scaphoid and triquetrum bones to provide temporary postoperative stability while a capsuloligamentous system forms around the implant. The Ascension PyroCarbon Lunate is constructed of a high strength On-X® PyroCarbon layer deposited on a graphite substrate. The graphite is impregnated with tungsten making the Lunate implant radiopaque. The Ascension PyroCarbon Lunate is available in 5 sizes for use in left or right applications. Device components are provided sterile in individual packaging.

INTENDED USE:

The Ascension® PyroCarbon Lunate is intended for replacement of the lunate bone in the proximal carpal row of the wrist in the presence of:

- Avascular necrosis (Kienboch's disease)
- Localized osteoarthritic changes
- Long-Standing dislocations

BASIS OF SUBSTANTIAL EQUIVALENCE:

A comparison of the Ascension Lunate and the Swanson Titanium Carpal Implant (K864491) show similar design features, surgical technique and indications. The Ascension Lunate and the Ascension CMC (K061451) are made of the same material and both are intended to articulate with carpal bone.

Performance testing was performed on the Pyrocarbon Lunate. These test results demonstrate that the Ascension Lunate's strength and endurance are adequate to ensure device safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ascension Orthopedics, Inc.
% Ms. Debbie Stearns
Director, Clinical Affairs
8700 Cameron Road, #100
Austin, Texas 78754-3832

JUN 17 2008

Re: K080997
Trade/Device Name: Ascension PyroCarbon Lunate
Regulation Number: 21 CFR 888.3750
Regulation Name: Wrist joint carpal lunate polymer prosthesis
Regulatory Class: Class II
Product Code: KWN
Dated: April 4, 2008
Received: April 16, 2008

Dear Ms. Stearns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Debbie Stearns

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use Statement

510(K) Number: K080997

Device Name: Ascension® PyroCarbon Lunate

Indications for Use:

The Ascension® PyroCarbon Lunate is intended for replacement of the lunate bone in the proximal carpal row of the wrist in the presence of:

- Avascular necrosis (Kienboch's disease)
- Localized osteoarthritic changes
- Long-Standing dislocations

Prescription Use X
(Part 21 CFR 801Subpart B)

OR

Over-The-Counter Use
(Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. [Signature] for [Signature]
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080997